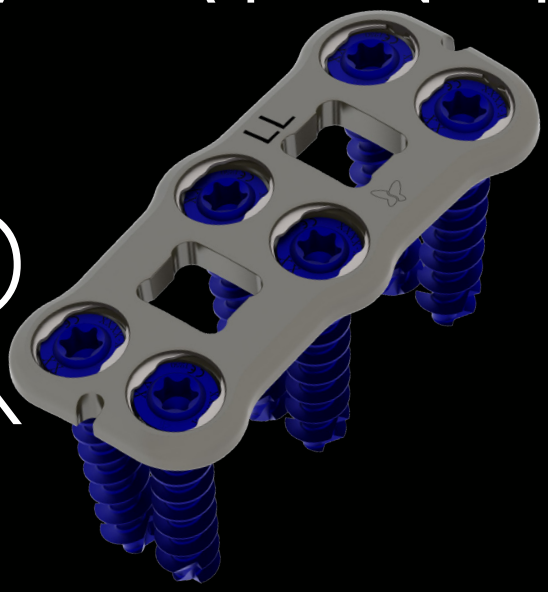
TRYPTIK®2 C-PLATE

BY SPINEART

ANTERIOR CERVICAL PLATE



CONTENT

CONCEPT AND DESIGN

The TRYPTIK®2 Cervical Plating System has been designed with surgeons in accordance with Spineart's motto : Quality, Innovation, Simplicity.

The TRYPTIK®2 C-PLATE system consists of sterile-packed implants and a single compact instrument set.

Pairing a one-step anti-backout mechanism with streamlined instrumentation, we are proud to offer to surgeons and operative room staff a practical handy solution for anterior cervical pathologies treatments.

AT A GLANCE

ANATOMICAL SHAPED

Pre-contoured, low-profile, smooth atraumatic surfaces.

EASE OF USE

Simple, one-step anti-backout mechanism.

INDICATIONS

TRYPTIK®2C-Plate Anterior Cervical Plate System is intended for use during anterior cervical discectomy with fusion, between C2 and C7, and up to 4 consecutive levels in skeletally mature patients. It is indicated for the surgical treatment of :

• Radiculopathy and/or myelopathy, secondary to cervical degenerative disc disease and/or spondylosis, and for patients that are resistant to conservative management;
• Traumatology.

IMPLANTS

SCREWS

SELF-DRILLING SCREW - VARIABLE ø4.0	
LENGTH 12	TRY-PD 40 12-S
LENGTH 14	TRY-PD 40 14-S
LENGTH 16	TRY-PD 40 16-S
LENGTH 18	TRY-PD 40 18-S

SELF-DRILLING SCREW - VARIABLE ø4.5	
LENGTH 12	TRY-PD 45 12-S
LENGTH 14	TRY-PD 45 14-S
LENGTH 16	TRY-PD 45 16-S
LENGTH 18	TRY-PD 45 18-S

SELF-TAPPING SCREW - VARIABLE ø4.0	
LENGTH 12	TRY-PS 40 12-S
LENGTH 14	TRY-PS 40 14-S
LENGTH 16	TRY-PS 40 16-S
LENGTH 18	TRY-PS 40 18-S
LENGTH 20*	TRY-PS 40 20-S
LENGTH 22*	TRY-PS 40 22-S

SELF-TAPPING SCREW - VARIABLE ø4.5	
LENGTH 12	TRY-PS 45 12-S
LENGTH 14	TRY-PS 45 14-S
LENGTH 16	TRY-PS 45 16-S
LENGTH 18	TRY-PS 45 18-S
LENGTH 20*	TRY-PS 45 20-S
LENGTH 22*	TRY-PS 45 22-S

PLATES

1-LEVEL PLATE	
LENGTH 20	TRY-CP 04 20-S
LENGTH 22	TRY-CP 04 22-S
LENGTH 24	TRY-CP 04 24-S
LENGTH 26	TRY-CP 04 26-S
LENGTH 28	TRY-CP 04 28-S
LENGTH 30	TRY-CP 04 30-S

2-LEVEL PLATE	
LENGTH 30	TRY-CP 06 30-S
LENGTH 32	TRY-CP 06 32-S
LENGTH 34	TRY-CP 06 34-S
LENGTH 36	TRY-CP 06 36-S
LENGTH 38	TRY-CP 06 38-S
LENGTH 40	TRY-CP 06 40-S
LENGTH 43	TRY-CP 06 43-S
LENGTH 46	TRY-CP 06 46-S
LENGTH 49	TRY-CP 06 49-S
LENGTH 52	TRY-CP 06 52-S

3-LEVEL PLATE	
LENGTH 49	TRY-CP 08 49-S
LENGTH 52	TRY-CP 08 52-S
LENGTH 55	TRY-CP 08 55-S
LENGTH 58	TRY-CP 08 58-S
LENGTH 61	TRY-CP 08 61-S
LENGTH 64	TRY-CP 08 64-S
LENGTH 68	TRY-CP 08 68-S
LENGTH 72	TRY-CP 08 72-S

4-LEVEL PLATE	
LENGTH 64*	TRY-CP 10 64-S
LENGTH 68*	TRY-CP 10 68-S
LENGTH 72	TRY-CP 10 72-S
LENGTH 76	TRY-CP 10 76-S
LENGTH 80	TRY-CP 10 80-S
LENGTH 84	TRY-CP 10 84-S
LENGTH 88	TRY-CP 10 88-S
LENGTH 92	TRY-CP 10 92-S

* Optional sizes

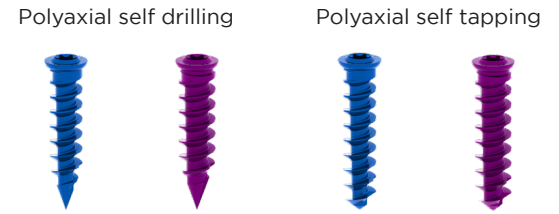
TECHNICAL FEATURES

PLATE

- The TRYPTIK®2 C-PLATE is made of Titanium alloy Ti6Al4V ELI, with elastic rings made of Nitinol NiTi.
- 1- 4 levels, plate lengths from 20-92mm
- 2.4mm thick, 16.5mm wide
- Lordotically pre-contoured
- Smooth surfaces decrease potential for soft tissue irritation
- Large graft viewing window
- Pre-contoured lordosis in the sagittal plane to allow lordosis

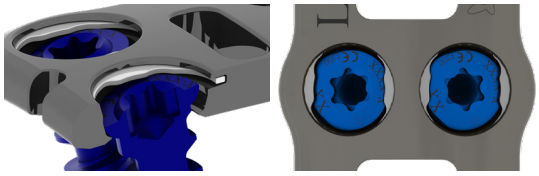
SCREW

- 15° cone of angulation
- Self-tapping and self-drilling options.
- Color coded diameter: 4.0mm (blue), 4.5mm (purple)
- 12-18mm lengths (2mm increment)
- Hexalobe recess provides greater torque transmission



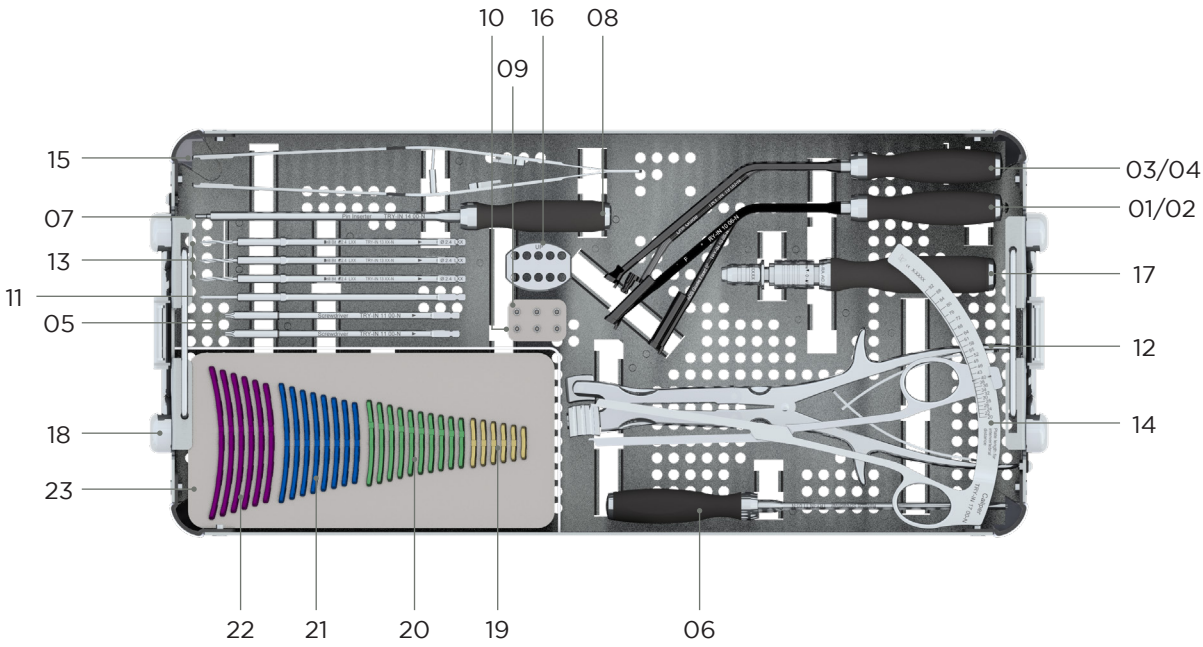
ANTI-BACKOUT SYSTEM

- One step
- Secured in the plate
- Locking ring expands, allowing screw head passage. Ring contracts after screw head advanced.
- Visual confirmation of screw retention
- Screw head placed completely below plate surface to decrease potential for soft tissue irritation



Lateral and anterior views of locking ring partially covering screw head.

INSTRUMENT SET



#	DESCRIPTION	REFERENCE
1	ADS* GUIDE, FIXED, 0°	TRY-IN 10 05-N
2	ADS* GUIDE, FIXED, 15°	TRY-IN 10 06-N
3	DRILL GUIDE	TRY-IN 19 00-N
4	DRILL GUIDE, FIXED, 15°	TRY-IN 22 00-N
5	SCREWDRIVER	TRY-IN 11 00-N
6	REVISION SCREWDRIVER	TRY-IN 11 01-N
7	PIN INSERTER	TRY-IN 14 00-N
8	PIN INSERTER INNER SHAFT	TRY-IN 14 01-N
9	TEMPORARY END PIN	TRY-IN 15 00-N
10	TEMPORARY HOLE PIN	TRY-IN 15 01-N
11	AWL	TRY-IN 12 00-N
12	PLATE BENDER	TRY-IN 16 00-N

#	DESCRIPTION	REFERENCE
13	DRILL BIT, ø2.4 L12	TRY-IN 13 12-N
	DRILL BIT, ø2.4 L14	TRY-IN 13 14-N
	DRILL BIT, ø2.4 L16	TRY-IN 13 16-N
14	CALIPER	TRY-IN 17 00-N
15	BAYONETED PLATE HOLDER	TRY-IN 18 00-N
16	SCREW BASE	TRY-IN 21 00-N
17	AO RATCHET HANDLE	HAN-RA AO 20-N
18	CONTAINER	TRY-BX 00 01-N
	OPTIONAL INSTRUMENTS	
19	PLATE TEMPLATE 1 LEVEL XX mm (COLOR: GOLD)	TRY-IN 04 XX-N
20	PLATE TEMPLATE 2 LEVEL XX mm (COLOR: GREEN)	TRY-IN 06 XX-N
21	PLATE TEMPLATE 3 LEVEL XX mm (COLOR: BLUE)	TRY-IN 08 XX-N
22	PLATE TEMPLATE 4 LEVEL XX mm (COLOR: PURPLE)	TRY-IN 10 XX-N
23	PLATE TEMPLATE RACK	TRY-BX 01 01-N

*Awl Drill Screwdriver

INSTRUMENTS

ADS GUIDE FIXED 0°	TRY-IN 10 05-N

ADS GUIDE FIXED 15°	TRY-IN 10 06-N

DRILL GUIDE FIXED 15°	TRY-IN 22 00-N

DRILL GUIDE	TRY-IN 19 00-N

BAYONETED PLATE HOLDER	TRY-IN 18 00-N

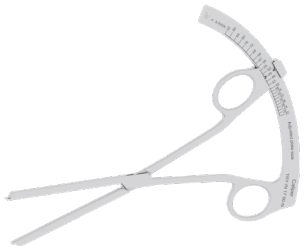
PLATE BENDER	TRY-IN 16 00-N

AO RATCHETING HANDLE	HAN-RA AO 20-N

AWL	TRY-IN 12 00-N

DRILL BIT 2.4 XX MM (STERILE)	TRY-IN 13 XX-S
DRILL BIT 2.4 XX MM (NON STERILE)	TRY-IN 13 XX-N

CALIPER	TRY-IN 17 00-N



INSTRUMENTS

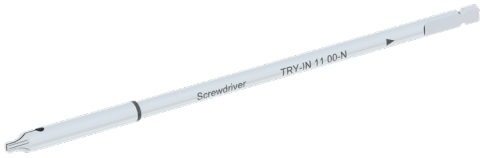
PIN INSERTER	TRY-IN 14 00-N

PIN INSERTER INNER SHAFT	TRY-IN 14 01-N

TEMPORARY END PIN (STERILE)	TRY-IN 15 00-S
TEMPORARY END PIN (NON STERILE)	TRY-IN 15 00-N

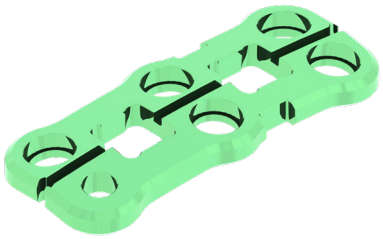
TEMPORARY HOLE PIN (STERILE)	TRY-IN 15 01-S
TEMPORARY HOLE PIN (NON STERILE)	TRY-IN 15 01-N

SCREWDRIVER	TRY-IN 11 00-N



REVISION SCREWDRIVER	TRY-IN 11 01-N

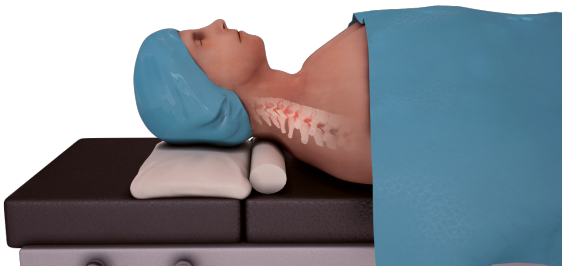
PLATE TEMPLATE	TRY-IN XX XX-N



SCREW BASE	TRY-IN 21 00-N

SURGICAL TECHNIQUE

STEP **1**



PATIENT POSITIONING

The patient is positioned on the table in supine position, with the head securely immobilized.
Confirm proper patient position by direct visualization and by radiographic images. Proceed with the standard approach and decompression if appropriate.

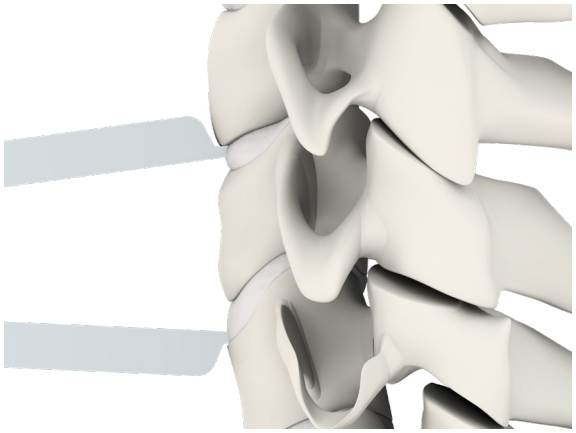
STEP **2**

IMPLANT SELECTION

Select the size of the implant to be used by measuring with the caliper.

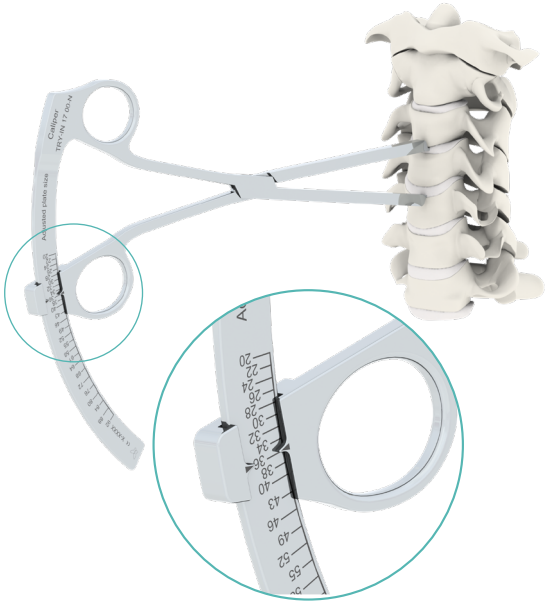
SURGICAL TECHNIQUE

STEP **2**



IMPLANT SELECTION

The caliper needs to sit on the inferior endplate of the most cephalad instrumented vertebra and on the superior endplate of the most caudal instrumented vertebra.



Select the plate size that corresponds to the measurement read on the caliper scale.
If between sizes, always choose the smaller size.

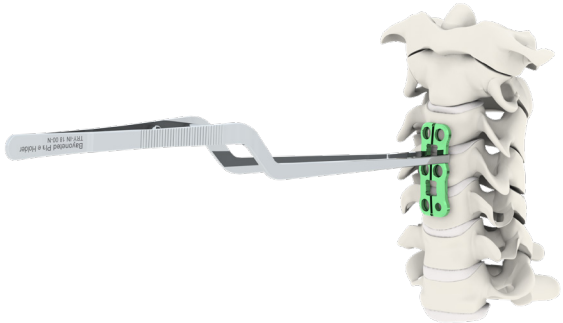
NOTE: The caliper is designed to indicate the total plate length, as shown on the implant package.

INSTRUMENT	REFERENCE
CALIPER	TRY-IN 17 00-N

TEMPLATING (OPTIONAL)

The selected plate size can be confirmed by using a corresponding template. Choose the appropriate template size from the template rack. Using the bayoneted plate holder, position the template at the midline of the level(s) to be treated and verify plate length.

NOTE: Do not bend the template.
CAUTION: Do not implant the plate template.



INSTRUMENTS	REFERENCE
PLATE TEMPLATE	TRY-IN XX XX-N
BAYONETED PLATE HOLDER	TRY-IN 18 00-N

SURGICAL TECHNIQUE

STEP **3**

PLATE BENDING

The TRYPTIK®2 C-PLATE is provided pre contoured. In some cases, the plate can be further contoured to better fit the patient's anatomy.
To modify the lordosis of the plate, the plate bender can be used.

WARNING: Ensure that the plate is not bent at plate hole positions to avoid locking ring damage and compromise.

INSTRUMENT	REFERENCE
PLATE BENDER	TRY-IN 16 00-N

STEP **4**

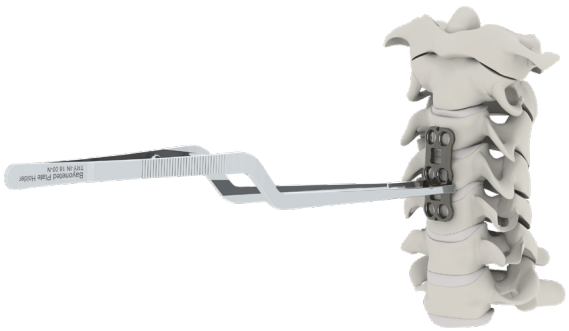


PLATE POSITIONING

The plate is positioned with the bayoneted plate holder on the level(s) to be treated.

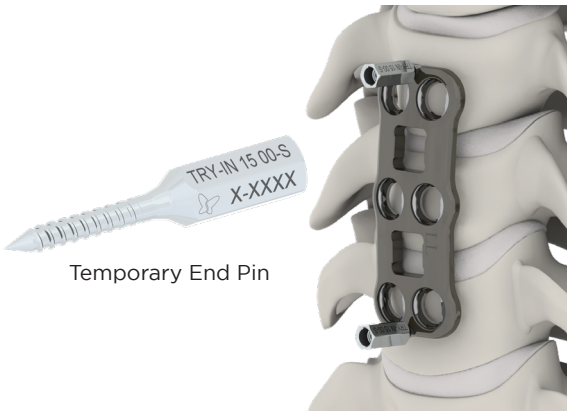
INSTRUMENT	REFERENCE
BAYONETED PLATE HOLDER	TRY-IN 18 00-N

SURGICAL TECHNIQUE

STEP **5**

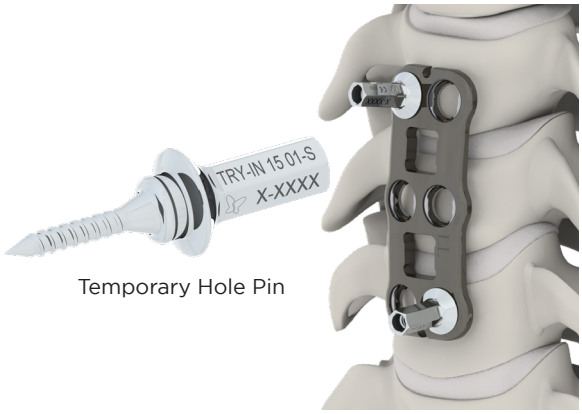
PIN SELECTION

Once the plate is in the desired position, the pins can be used to hold the plate in place. Two types of pins are available, depending on the surgeon preference:



Temporary End Pin

Temporary End Pin, to be positioned at the cranial and caudal extremities of the plate, and inserted through the notches, perpendicular to the plate.



Temporary Hole Pin

Temporary Hole Pin, to be positioned within the screw holes.

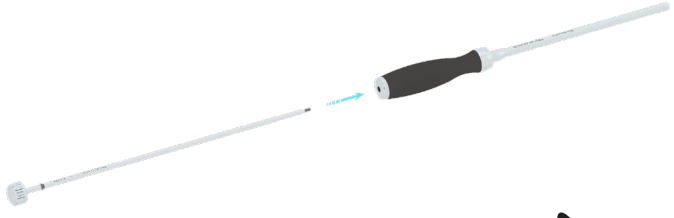
Both pin options are provided in a sterile and non-sterile version.

The diameter of the pin shaft is 1.6mm, and length beyond the plate is 10 mm.

NOTE: It is recommended to use two pins at each plate extremity, in order to avoid any shift or rotation of the plate during pilot hole drilling.

PIN INSERTER ASSEMBLY

Insert the pin inserter inner shaft into the pin inserter. Advance the first part of the thread into the pin inserter handle.



SURGICAL TECHNIQUE

STEP **5**

PIN PLACEMENT

To insert either the temporary end pin or the temporary hole pin, connect the pin to the pin inserter turning clockwise the knob located on the handle.

Proceed to penetrate the bone cortex with the pin. Unlock the pin from the pin inserter by turning the pin inserter knob counterclockwise.

Attach the next pin to the pin inserter and repeat the pin insertion procedure.

Once the plate is securely in place with the aid of the pins, the screw preparation can start.

DISPOSABLE STERILE INSTRUMENTS	REFERENCE
TEMPORARY END PIN (STERILE)	TRY-IN 15 00-S
TEMPORARY HOLE PIN (STERILE)	TRY-IN 15 01-S

INSTRUMENTS	REFERENCE
TEMPORARY END PIN (NON STERILE)	TRY-IN 15 00-N
TEMPORARY HOLE PIN (NON STERILE)	TRY-IN 15 01-N
PIN INSERTER	TRY-IN 14 00-N
PIN INSERTER INNER SHAFT	TRY-IN 14 01-N

SURGICAL TECHNIQUE

STEP **6**

Drill guide

Drill guide fixed 15°

ADS double barrel guide 0°

ADS double barrel guide 15°

SCREW PATH PREPARATION

Appropriate pilot hole determination is key to proper screw placement and to secure the screw with the anti-backout mechanism.

The TRYPTIK®2 C-PLATE system offers 4 possibilities to prepare the screw path:

Option 1: Drill guide
Option 2: Drill guide fixed 15°
Option 3: ADS* double barrel guide 0°
Option 4: ADS double barrel guide 15°

For each of these options the awl and drill step will be mandatory.

You will find the description of these 4 options in the next pages .

INSTRUMENTS	REFERENCE
DRILL GUIDE	TRY-IN 19 00-N
DRILL GUIDE, FIXED, 15°	TRY-IN 22 00-N
ADS GUIDE, FIXED, 0°	TRY-IN 10 05-N
ADS GUIDE, FIXED, 15°	TRY-IN 10 06-N

*Awl Drill Screwdriver

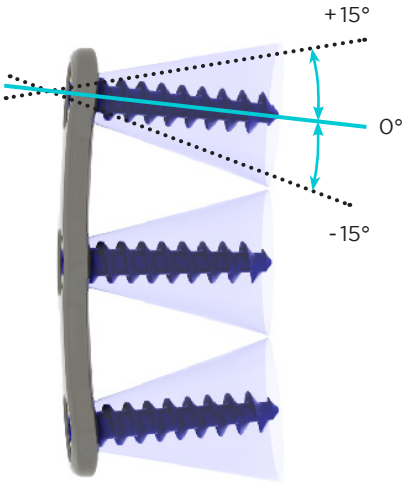
SURGICAL TECHNIQUE

STEP **6**

SCREW PATH PREPARATION

NOTE: It is recommended to insert the screw sequentially at opposite plate corners.

This helps to secure the plate in position on the vertebrae, thus ensuring proper screw placement.



WARNING: Maximum screw angulation must not exceed 15°.

SURGICAL TECHNIQUE

OPTION 1: FREE HAND SINGLE BARREL DRILL GUIDE

STEP **6**

SCREW PATH PREPARATION – AWL

Insert the drill guide into the desired plate hole.

Ensure that the drill guide is securely connected to the plate hole to avoid damage to the locking mechanism.

To confirm proper alignment, visually check that the handle of the drill guide is parallel to the plate longitudinal axis.

Connect the AO handle to the awl and insert it through the drill guide to perforate the cortex of the bone. The awl tip length is 10mm. Repeat the step for all plate holes.

WARNING: Always use the awl with the guide. If not, the screw could be at an angulation that will not permit the screw capture by the locking ring.

NOTE: If temporary pins are inserted in the plate holes, remove one pin at a time prior to positioning the drill guide in the plate hole.

WARNING: Always use the awl with the guide. If not awl depth into the bone could be too long.

INSTRUMENTS	REFERENCE
AO HANDLE	HAN-SI AO 20-N
DRILL GUIDE	TRY-IN 19 00-N
AWL	TRY-IN 12 00-N

SURGICAL TECHNIQUE

OPTION 1: FREE HAND SINGLE BARREL DRILL GUIDE

STEP **6**

SCREW PATH PREPARATION – DRILLING

Once the cortex is penetrated with the awl, remove the awl while keeping the drill guide in place.

Select the drill bit of the desired length and connect it to the AO handle.
Introduce the drill bit through the drill guide to prepare the path for the screw insertion. Repeat the step for all plate holes. If temporary pins are inserted in the plate holes, remove the pin prior to positioning the drill guide in the plate hole.

NOTE: Prior to removing the temporary pins, maintain the plate in the desired position before inserting the screws in the free holes.

The drill bit will stop against the drill guide at the length corresponding to the drill bit size.

At this step, confirm radiographically the desired screw length.

NOTE: Insert a screw immediately after preparation of pilot holes, as described in step 7.

DISPOSABLE STERILE INSTRUMENTS	REFERENCE
DRILL BIT, ø2.4 L12	TRY-IN 13 12-S
DRILL BIT, ø2.4 L14	TRY-IN 13 14-S
DRILL BIT, ø2.4 L16	TRY-IN 13 16-S

INSTRUMENTS	REFERENCE
AO HANDLE	HAN-SI AO 20-N
DRILL GUIDE	TRY-IN 19 00-N
DRILL BIT, ø2.4 L12	TRY-IN 13 12-N
DRILL BIT, ø2.4 L14	TRY-IN 13 14-N
DRILL BIT, ø2.4 L16	TRY-IN 13 16-N

SURGICAL TECHNIQUE

OPTION 2: DRILL GUIDE FIXED 15°

STEP **6**

Use this option to prepare the screw path at the caudal or cephalad part of the plate.

SCREW PATH PREPARATION – AWL

Insert the drill guide fixed 15° into the desired plate hole. Ensure that the drill guide fixed 15° is securely connected to the plate hole in order to avoid any potential damage to the locking mechanism of the plate.
To confirm proper alignment, visually check that the handle of the drill guide is parallel to the plate longitudinal axis.

Connect the AO handle to the awl and introduce it through the drill guide fixed 15° to perforate the cortex of the bone.

WARNING: Always use the awl with the guide. If not, the screw could be at an angulation that will not permit the screw capture by the locking ring.

NOTE: If temporary pins are inserted in the plate holes, remove one pin at a time prior to positioning the drill guide in the plate hole.

WARNING: Always use the awl with the guide. If not awl depth into the bone could be too long.

INSTRUMENTS	REFERENCE
AO HANDLE	HAN-SI AO 20-N
DRILL GUIDE FIXED 15°	TRY-IN 22 00-N
AWL	TRY-IN 12 00-N

SURGICAL TECHNIQUE

OPTION 2: DRILL GUIDE FIXED 15°

STEP **6**

SCREW PATH PREPARATION – DRILLING

Once the cortex is penetrated with the awl, remove the awl while keeping the drill guide fixed 15° in place.

Select the drill bit of the desired length and connect it to the AO handle.
Introduce the drill bit through the drill guide fixed 15° to prepare the path for the screw insertion.

The drill bit will stop against the drill guide at the length corresponding to the drill bit size.

At this step, confirm radiographically the desired screw length.

NOTE: If temporary pins are inserted in the plate holes, remove one pin at a time prior to positioning the drill guide in the plate hole.
Insert a screw immediately after preparation of pilot holes, as described in step 7.

DISPOSABLE STERILE INSTRUMENTS	REFERENCE
DRILL BIT, ø2.4 L12	TRY-IN 13 12-S
DRILL BIT, ø2.4 L14	TRY-IN 13 14-S
DRILL BIT, ø2.4 L16	TRY-IN 13 16-S

INSTRUMENTS	REFERENCE
AO HANDLE	HAN-SI AO 20-N
DRILL GUIDE FIXED 15°	TRY-IN 22 00-N
DRILL BIT, ø2.4 L12	TRY-IN 13 12-N
DRILL BIT, ø2.4 L14	TRY-IN 13 14-N
DRILL BIT, ø2.4 L16	TRY-IN 13 16-N

SURGICAL TECHNIQUE

OPTION 3: DOUBLE BARREL ADS GUIDE FIXED 0°

STEP **6**

Use this option to prepare the screw path at the middle of the 2+ levels plate.

SCREW PATH PREPARATION – AWL

Insert the ADS guide fixed 0° into the desired plate hole. Ensure that the ADS guide fixed 0° is securely connected to the plate hole to avoid any potential damage to the locking mechanism of the plate.
To confirm proper alignment, visually check that the handle of the drill guide is parallel to the plate longitudinal axis.

Connect the AO handle to the awl and introduce it through the ADS guide fixed 0° to perforate the cortex of the bone.

WARNING: Always use the awl with the guide. If not, the screw could be at an angulation that will not permit the screw capture by the locking ring.

NOTE: If temporary pins are inserted in the plate holes, remove one pin at a time prior to positioning the drill guide in the plate hole.

WARNING: Always use the awl with the guide. If not awl depth into the bone could be too long.

INSTRUMENTS	REFERENCE
AO HANDLE	HAN-SI AO 20-N
ADS DRILL GUIDE FIXED 0°	TRY-IN 10 05-N
AWL	TRY-IN 12 00-N

SURGICAL TECHNIQUE

OPTION 3: DOUBLE BARREL ADS GUIDE FIXED 0°

STEP **6**

SCREW PATH PREPARATION – DRILLING

Once the cortex is penetrated with the awl, remove the awl while keeping the ADS guide fixed 0° in place.

Select the drill bit of the desired length and connect it to the AO handle.
Introduce the drill bit through the ADS guide fixed 0° to prepare the path for the screw insertion.

The drill bit will stop against the drill guide at the length corresponding to the drill bit size.

At this step, confirm radiographically the desired screw length.

NOTE: insert a screw immediately after preparation of pilot holes, as described in step 7.

DISPOSABLE STERILE INSTRUMENTS	REFERENCE
DRILL BIT, ø2.4 L12	TRY-IN 13 12-S
DRILL BIT, ø2.4 L14	TRY-IN 13 14-S
DRILL BIT, ø2.4 L16	TRY-IN 13 16-S

INSTRUMENTS	REFERENCE
AO HANDLE	HAN-SI AO 20-N
ADS DRILL GUIDE FIXED 0°	TRY-IN 10 05-N
DRILL BIT, ø2.4 L12	TRY-IN 13 12-N
DRILL BIT, ø2.4 L14	TRY-IN 13 14-N
DRILL BIT, ø2.4 L16	TRY-IN 13 16-N

SURGICAL TECHNIQUE

OPTION 4 : DOUBLE BARREL ADS GUIDE FIXED 15°

STEP **6**

Use this option to prepare the screw path at the caudal or cephalad part of the plate.

SCREW PATH PREPARATION – AWL

Insert the ADS guide fixed 15° into the desired plate hole. Ensure that the ADS guide fixed 15° is securely connected to the plate hole to avoid any potential damage to the locking mechanism of the plate.
To confirm proper alignment, visually check that the handle of the drill guide is parallel to the plate longitudinal axis.

Connect the AO handle to the awl and introduce it through the ADS guide fixed 15° to perforate the cortex of the bone.

WARNING: Always use the awl with the guide. If not, the screw could be at an angulation that will not permit the screw capture by the locking ring.

NOTE: If temporary pins are inserted in the plate holes, remove one pin at a time prior to positioning the drill guide in the plate hole

WARNING: Always use the awl with the guide. If not awl depth into the bone could be too long.

INSTRUMENTS	REFERENCE
AO HANDLE	HAN-SI AO 20-N
ADS DRILL GUIDE FIXED 15°	TRY-IN 10 06-N
AWL	TRY-IN 12 00-N

SURGICAL TECHNIQUE

OPTION 4 : DOUBLE BARREL ADS GUIDE FIXED 15°

STEP **6**

SCREW PATH PREPARATION – DRILLING

Once the cortex is penetrated with the awl, remove the awl while keeping the ADS guide fixed 15° in place.

Select the drill bit of the desired length and connect it to the AO handle.
Introduce the drill bit through the ADS guide fixed 15° to prepare the path for the screw insertion.

The drill bit will stop against the drill guide at the length corresponding to the drill bit size.

At this step, confirm radiographically the desired screw length.

NOTE: insert a screw immediately after preparation of pilot holes, as described in step 7.

DISPOSABLE STERILE INSTRUMENTS	REFERENCE
DRILL BIT, ø2.4 L12	TRY-IN 13 12-S
DRILL BIT, ø2.4 L14	TRY-IN 13 14-S
DRILL BIT, ø2.4 L16	TRY-IN 13 16-S

INSTRUMENTS	REFERENCE
AO HANDLE	HAN-SI AO 20-N
ADS DRILL GUIDE FIXED 15°	TRY-IN 10 06-N
DRILL BIT, ø2.4 L12	TRY-IN 13 12-N
DRILL BIT, ø2.4 L14	TRY-IN 13 14-N
DRILL BIT, ø2.4 L16	TRY-IN 13 16-N

SURGICAL TECHNIQUE

STEP **7**

SCREW LOADING

Connect the AO handle to the screwdriver shaft and load the desired screw using the screw base.

NOTE: According to surgeon preference, the following screw options are available: variable self drilling or self tapping.

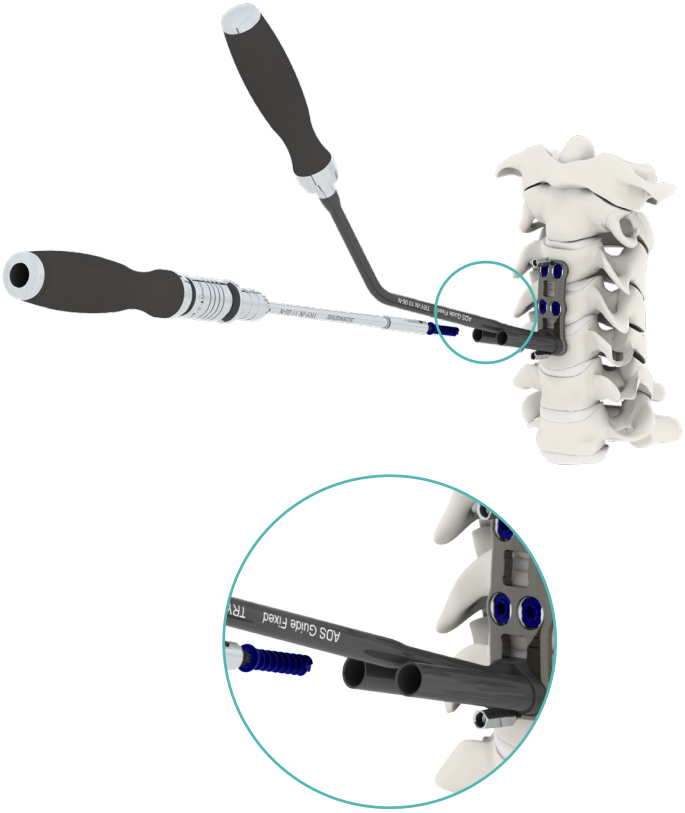
SCREW INSERTION – OPTION 1 & 2

Advance the screw in the bone without allowing the locking ring to capture the screw head.

INSTRUMENTS	REFERENCE
SCREWDRIVER	TRY-IN 11 00-N
AO HANDLE	HAN-SI AO 20-N
SCREW BASE	TRY-IN 21 00-N

SURGICAL TECHNIQUE

STEP **7**



SCREW INSERTION – OPTION 3 & 4

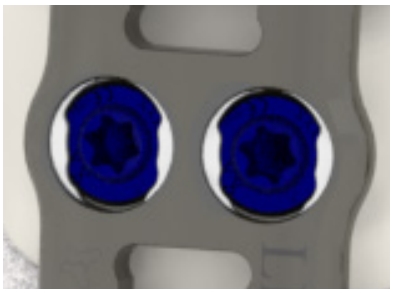
Advance the screw in the bone until the screwdriver laser etching is flush with the ADS guide upper border.

At this point the screw is in the plate but the locking ring has not fully captured the screw head.

INSTRUMENTS	REFERENCE
SCREWDRIVER	TRY-IN 11 00-N
AO HANDLE	HAN-SI AO 20-N
ADS DRILL GUIDE, FIXED, 15°	TRY-IN 21 00-N

SURGICAL TECHNIQUE

STEP **8**



FINAL INSERTION

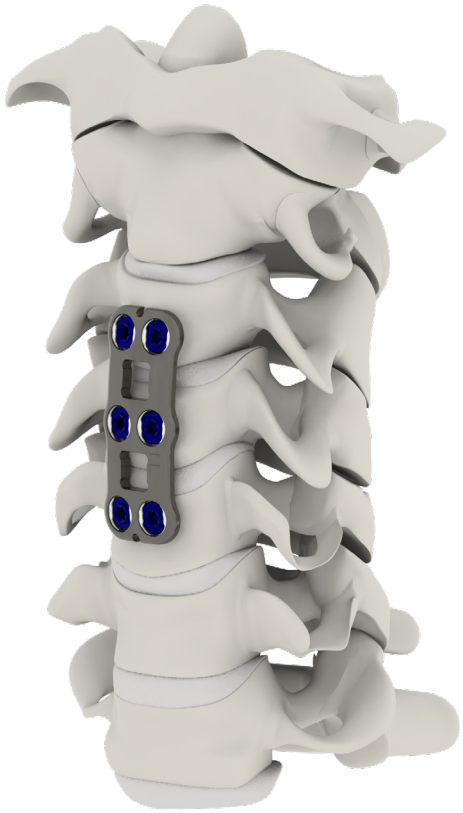
Repeat the step for each plate hole, until all screws are in place.

Proceed to remove the temporary pins.

Final tighten all the screws so that they are captured by the locking ring.

NOTE: Visually verify that the locking rings are partially covering the screw head, like in the image.

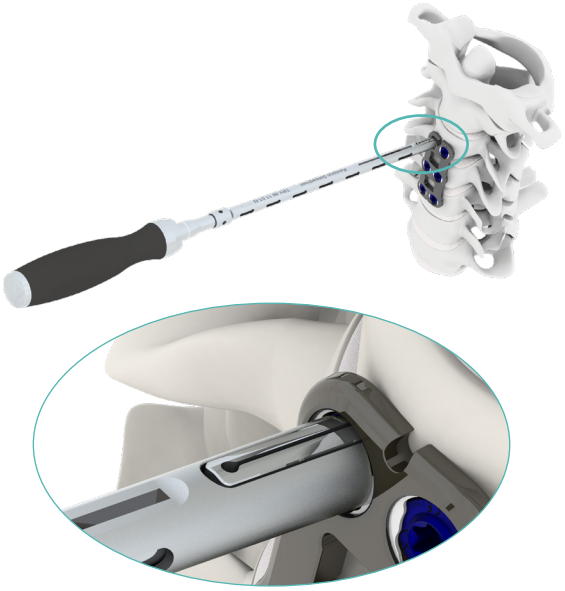
FINAL CONSTRUCT



Before closing, confirm visually that all locking rings are correctly positioned above the screw head.

SURGICAL TECHNIQUE

PLATE REMOVAL



SCREW ATTACHMENT

Place the Revision screwdriver on the desired screw and align the black laser mark with the cephalocaudal axis.
While pushing down, slightly turn the screwdriver to engage properly the end tip of the screwdriver into the screw head.

WARNING: Removal of the screw could affect the locking ring integrity. Carefully check the ring integrity before placing another screw at the same location.

SCREW REMOVAL

Unscrewing the screw will automatically disengage the locking ring.

Repeat these steps for all the screws.

PLATE REMOVAL

Once all the screws are removed, remove the plate with the plate holder.

INSTRUMENT	REFERENCE
REVISION SCREWDRIVER	TRY-IN 11 01-N

GENERAL INFORMATION

STERILITY

The implant is provided sterile. Under sterile condition, implants are packaged in a first polyethylene pouch, put in a second polyethylene pouch. Each of these packaging are labeled and an IFU is included.

CAUTION

If the implant or its packaging seems to be damaged, if the expiry date is exceeded or if the sterility cannot be guaranteed for any reason, the implant mustn't be used. The re-sterilization of the gamma sterilized implant is forbidden. The TRYPTIK®2C-Plate implant must not be used with implant other than TRYPTIK®2C-Plate range. The TRYPTIK®2C-Plate implant must only be used with the TRYPTIK®2C-Plate instruments.
Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the cervical plate system.
Do not use titanium and stainless steel components together.
Components of TRYPTIK®2C-Plate system should not be used with components of any other system or manufacturer.

DESCRIPTION

The TRYPTIK®2C-Plate implant range was designed to ensure the best possible adaptation to the patient's anatomic variations.
TRYPTIK®2C-Plate Anterior Cervical Plate System consists of various sizes of bones plates, screws and surgical instruments. The screws are used to secure the plates to the vertebral bodies of the cervical spine through an anterior approach. The plates have an integrated locking mechanism that captures the screw upon full insertion, preventing screw-backout. Plates and screws are manufactured from titanium alloy (ASTM F 136) and nitinol alloy (ASTM F 2063). Plates and screws are supplied sterile.

INDICATIONS

TRYPTIK®2C-Plate Anterior Cervical Plate System is intended for use during anterior cervical discectomy with fusion, between C2 and C7, and up to 4 consecutive levels in skeletally mature patients. It is indicated for the surgical treatment of:

- Radiculopathy and/or myelopathy, secondary to cervical degenerative disc disease and/or spondylosis, and for patients that are resistant to conservative management;
- Traumatology;

CONTRAINDICATIONS

Include but not limited to:

- Mental illness.
- Infection.
- Severely damaged bone structures that could prevent stable implantation of the plate system.
- Neuromuscular or vascular disorders or illness.
- Inadequate activity.
- Pregnancy.
- Bone tumor in the region of implant.
- Suspected or documented metal allergy or intolerance.

SIDE EFFECTS

Per operative :
Pharyngeal or esophageal laceration, thoracic duct injury, vertebral artery laceration, carotid artery or jugular vein injury, dural laceration, CSF leakage, nerve root lesion.

Post operative :
Dysphagia, pseudarthrosis, recurrent laryngeal nerve (RLN) palsy, Horner syndrome, postoperative aneurysm formation, postoperative epidural hematoma, postoperative wound hematoma, respiratory insufficiency, angioedema, superficial wound infection, deep wound infection, epidural abscess, spondylodiscitis, aseptic spondylodiscitis, seroma, meningitis, spinal cord contusion, transient or permanent myelopathy, additional radicular symptoms.

Specific to implant:
Implant migration, adhesion and fibrosis, limited range of movement, secondary fractures.
Potential risk identified with the use of this cervical anterior plate device, which may require additional surgery, include: device component fracture, loss of fixation, pseudarthrosis (i.e., non–union), fracture of the vertebra, neurological injury, and vascular injury.

CAUTION – PRECAUTION FOR USE

An in-depth discussion of all possible complications associated with cervical anterior plate system is beyond the scope of these instructions. Every surgeon who uses these implants must take each patient's clinical state and medical status into consideration, and be fully familiar with procedures involving the use of this type of implant and the potential complications in each case.
Implants are mechanical devices that can be worn, damaged or broken. An implant site can become infected, painful, swollen, or inflamed. Significant weight on the implant, an implant of inadequate size, and patient hyperactivity or a misuse will increase the risk of complications, including wear and tear or rupture.

GENERAL INFORMATION

The soft tissue and the adjacent bones may deteriorate over time, or may not be in an adequate state to support the implant, thus causing instability and/or malformation. The benefits of this cervical anterior plate procedure may not meet the patient's expectations, thus requiring more surgery to replace or remove the implant, or other types of procedures. Surgeons should therefore take several factors into consideration, in order to achieve optimal results for each patient. It is therefore essential that each patient who must undergo this type of procedure be informed, with the supporting documentation available, of the potential complications.
The TRYPTIK®2C-Plate system has not been evaluated for safety and compatibility in the MR environment. The TRYPTIK®2C-Plate system has not been tested for heating, migration, or image artifact in the MR environment. The safety of TRYPTIK®2C-Plate system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

HANDLING

No effort has been spared to ensure that only the highest-quality materials and expertise have been deployed in producing each implant. When handling these implants, blunt instruments should be used in order to avoid scratching, cutting, or nicking the device. Sharp-edged, serrated or toothed instruments should not be used. Careful preparation of the surgical site and choosing an implant of the right size will increase the chances of a successful reconstruction.

SURGERY METHODS

Precaution: the implantation of cervical anterior plate should be performed only by experienced surgeons with specific training in the use of this cervical anterior plate because this is a technically demanding procedure presenting risk of serious injury to the patient.
The surgeon is responsible for familiarizing him/herself with the surgical technique used for implanting these devices, by studying the relevant published articles, consulting experienced colleagues, and receiving training in the methods appropriate to the particular implant being used. We strongly recommend that excessive force should not be applied when installing any of the TRYPTIK®2C-Plate implants.
A handbook on surgical techniques, describing the standard implant procedure, is available.

PATIENT CARE FOLLOWING TREATMENT

Detailed instructions on the use and limitations of the device should be given to the patient. Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician. The patient should be instructed regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient.

STORAGE CONDITIONS

It is mandatory that the implants are stored in their original packaging, in a clean, dry location where atmospheric pressure is moderate.

INSTRUMENTATION

The instruments were specifically designed for use when installing the TRYPTIK®2C-Plate implants.
They are delivered non-sterile.

DECONTAMINATION, CLEANING, AND STERILIZATION

Point-of-instruction: The instruments must, immediately after use, be decontaminated, cleaned, and sterilized as described below.
Prior to starting the surgical procedure, all non sterile reusable instruments must be properly cleaned, decontaminated and sterilized.

These instruments have been designed in order to avoid disassembly manipulation prior decontamination, cleaning and sterilization processes.

These methods and parameters have been validated following the AAMI TIR 30 Technical Report for reusable instruments and not sterile implants.

Manual disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 1 minute, using soft-bristled brush to assist in the removal of gross soil debris. The devices which can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 5 minutes using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute.
- Use a syringe to flush the devices with cannulation with 2x20 ml of neutral enzymatic cleaner at room temperature (+15/+25°C).
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).

GENERAL INFORMATION

- Rinse devices under running cold water for 1 minute. Devices with mobile parts will be activated during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 2 minutes using soft-bristled brush at room temperature (+15/+25°C).
- Use a syringe to flush the devices with cannulation with 2x20 ml of deionized water at room temperature (+15/+25°C).
- Rinse thoroughly the devices with deionized water for 2 minutes. Devices with mobile parts will be activated during rinsing.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

Automatic disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 30 seconds, using soft-bristled brush to assist in the removal of gross soil debris. The devices which can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 1 minute using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 30 seconds. Devices with mobile parts will be activated during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute. Devices with mobile parts will be activated during rinsing.
- Load devices into the washer-disinfector.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

WASHER-DISINFECTOR PARAMETERS			
Step	**Solution**	**Temperature**	**Time**
Pre-cleaning	Water	<45°	2 minutes
Cleaning	Water + Neutral enzymatic cleaner (as example NEO-DISHER Mediclean Forte)	55°C	10 minutes
Neutralizing	Water	<45°	2 minutes
Rinsing	Tap water	<45°	2 minutes
Thermal disinfection	Reversed osmosis water	90 °C	5 minutes

Sterilization trays cleaning and disinfection

All the trays must be thoroughly cleaned and disinfected after surgery completion.

Cleaning recommendations

- Remove all the instruments from the trays,
- Large and visible impurities must be removed from the trays,
- Use running water and rinse thoroughly for at least one minute,
- Use freshly prepared cleaning bath of the specified concentration for the period specified by the manufacturer,
- Use soft brush until there is no visible contamination,
- Dry trays with lint-free disposable cloths.

Disinfection recommendations

- Use a freshly disinfectant bath of the specified concentration for the period specified by the manufacturer. Rinse thoroughly three times,
- Rinse trays thoroughly with water as specified by the disinfectant manufacturer,
- Dry trays with lint-free disposable cloths.

Trays must be visually clean, if not, repeat the cleaning and disinfection protocol.

GENERAL INFORMATION

Subsequent sterilization in containers is recommended, using an autoclave and steam, and following a protocol that meets the minimum requirements or more, and is in compliance with current legislation (e.g., 134°C – 18 minutes) to obtain a guaranty of sterility of 10-6.The validation for sterilization have been done according to overkill/ half cycle method as described in the ISO 17664, ISO 17665 standards and of AAMI TIR 12 Technical Report.
Whenever applicable, implants delivered into non sterile condition must follow the same protocol of decontamination, cleaning and sterilization.

Sterilization parameters
Method: Pre-vacuum cycle of Steam sterilization (moist heat - autoclave)
Cycle 1 (EU):
Exposure time: 18 minutes
Temperature: 134°C
Drying time: 30 minutes
Cycle 2 (USA):
Exposure time: 4 minutes
Temperature: 132°C
Drying time: 30 minutes

"Do not stack trays during sterilization"

PRODUCT USE LIFE

Spineart® instruments are validated for 150 steam sterilization runs.
Prior to use all components should be checked for functionality and the absence of defects such as wear, tear, corrosion, pitting and discoloration to ensure that there is no damage.
Damaged components must not be used and should be returned to Spineart®.

MAINTENANCE AND REPAIRING

Spineart® instruments that need to be repaired must be decontaminated and cleaned, then sent to the address mentioned in this document.

FURTHER INFORMATION

If further directions for use of this system are needed, please check with the Spineart® Customer Service. If further information is needed or required, please see the addresses on this document.

spineart.com

OCT 2018 ref: TRY-BR Niti 31-E CE 1250

DOCUMENT NOT VALID FOR THE US

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